

REMARKS

Claims 1 – 51 are pending in this application. Claims 1 – 4, 11 – 30, 33 – 36, 38 – 40, 48, 50, and 51 stand objected to under 35 USC 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 2, 18, 20, 26, 34, 35, 36, 39, and 40 stand rejected under 35 USC 102(b) as anticipated by US Patent 5,024,223 (Chow). Claims 3, 23, 25, 27, 28, 33, 50, and 51 stand rejected under 35 USC 103(a) as being unpatentable over Chow in view of US Patent 6,038,480 (Hrdlicka). Claims 3, 23, 25, 27, 28, 33, 50, and 51 stand rejected under 25 USC 103(a) over Chow in view of US Patent 6,393,327 (Scribner). Claims 4, 22, 24, 29, 30, and 38 stand rejected under 35 USC 103(a) as being unpatentable over Chow. Claim 33 stands objected to under 35 USC 101 (Double Patenting) as being substantially the same invention as claim 28. Claim 16 stands objected to under 35 USC 101 (Double Patenting) as being substantially the same invention as claim 17.

Claim 5 – 10, 17, 31 – 33, 37, 41 – 47, and 49 are withdrawn without prejudice in response to the restriction requirement, and to the double patenting rejection. Applicant elects group I drawn to an electrode array body. Applicant has addressed the Examiner's objections under 35 USC 112 as follows: In claim 1, "curved such that it substantially conforms" is changed to "adapted to conform". In claim 2, "the body for attaching the electrode array to the retina" is changed to "said flexible body suitable for attaching said flexible body to the retina". In claim 3, "... a radius of spherical curvature, which approximates the curvature of the eye, that is decreasing near its edges thus causing the edge of the array..." has been changed to "... at least one radius of spherical curvature, which approximates the curvature of the eye, said radius decreasing near edges of said flexible body thus causing said edges of said flexible body ...". In claim 11, "... having, a strain relief slot in the oval shaped body curved part of the way around the aperture which defines a strain relief internal tab for relief of stresses formed when the electrode array body is attached to the retina of the recipient." has been changed to "... further comprising a strain relief slot in said oval shaped flexible body forming a semicircular opening around said mounting aperture which defines a strain relief internal tab in said flexible body for relief of stresses." Equivalent changes have been made to the remaining claims as well as

numerous additional changes to better point out applicant's invention and conform the claims to 35 USC 112. The changes are best understood by reviewing the mark up of changes following this amendment.

With respect to the rejections under 35 USC 102 and 103, the structure of the Chow electrode array is a silicon semiconductor chip. The silicon semiconductor chip described in Chow is flat and rigid. Figure 1d of Chow shows multiple rigid sections that grossly approximate the curvature of the eye, but are not conformal to the eye as a flexible array body would be. This demonstrates not only that it is unobvious to curve the Chow structure, but also that Chow was unable to achieve a curved structure using rigid silicon ceramic.

The structure of the Scribner array is glass. While the glass can be curved, it is necessarily rigid, lacking all of the benefits of our conformal array. A curved rigid electrode array is preferable over a flat rigid electrode array, but still less effective than a curved flexible array. It is not clear what material is used in the structure of the Hrdlicka array, the description of the preferred embodiment begins, "Referring to FIG. 1, a preferred form of flat paddle...." While Hrdlicka has curved edges, the array is flat in the plane of the electrodes. It is the plane of the electrode array that must conform to the retina. Hrdlicka's flat array with curved edges does not conform to the spherical surface of the retina. Furthermore, Hrdlicka is silent as to the importance of curving the edges any amount past the curvature of any particular structure, such as the retina. Also, on these microscopic dimensions it is difficult or impossible to control the edge geometry of rigid substrates such as silicon or glass. The applicant was unsuccessful after many attempts to produce such curvatures in silicon ceramic. However, in flexible materials, such as a silicone polymer, we were successful.

The retina is a delicate living tissue structure. It is often described as having the texture and strength of wet tissue paper. The retina is generally spherical but includes many complex variations from spherical, such as the dip with a radius of curvature change at the fovea. Further, retinas are as unique as fingerprints. No two retinas are shaped the same. An effective retinal electrode array must not only follow the general spherical shape of the retina, but must also be flexible enough to gently mold to the contours of the individual retina. An electrode array

curved in the plane of the retina that gently molds to the contours of the retina is not disclosed in the prior art, either individually or in combination. Applicant has added the limitation that the array body is flexible to each independent claim.

If for any reason the Examiner finds the application other than in condition for allowance, and the Examiner believe that a teleconference may be helpful, the Examiner is invited to call the undersigned attorney at (661) 775-3990 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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Date

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Markup of Changes.

Please amend claim 1 to read as follows:

1. (Amended) An electrode array body comprising:
a flexible body having a generally oval shape in the plane of ~~the~~ a retina,
the oval shaped flexible body being ~~curved such that it substantially conforms adapted to~~
conform to the spherical curvature of the retina of the recipient's eye thus minimizing stress
concentration ~~in the retina~~.

Please amend claim 2 to read as follows:

2. (Amended) ~~An~~ The electrode array body ~~as in~~ according to claim 1 further comprising:
at least one mounting aperture in ~~the said flexible body~~ suitable for attaching ~~the electrode~~
~~array~~ said flexible body to the retina with a tack.

Please amend claim 3 to read as follows:

3. (Amended) ~~An~~ The electrode array body ~~as in~~ according to claim 2 wherein,
~~the said~~ oval shaped flexible body has ~~a~~ at least one radius of spherical curvature, which
approximates the curvature of the eye, ~~that is~~ said radius decreasing near ~~its~~ edges of said
flexible body thus causing ~~the edge~~ said edges of the array said flexible body to lift off of the
retina, eliminating stress concentrations in the retina from contact with ~~the electrode array~~ said
flexible body.

Please amend claim 4 to read as follows:

4. (Amended) ~~An~~ The electrode array body ~~as in~~ according to claim 3 wherein,
~~the said~~ oval shaped flexible body is made of silicone having a hardness of about 50 or less
on the Shore A scale as measured with a durometer.

Please delete claim 5.

~~5. A method of reducing stress in the retina caused by the electrode array body as in claim 2 wherein,~~

~~—forming a strain relief internal tab by placing a strain relief slot partially around the mounting aperture.~~

Please delete claim 6.

~~6. An electrode array body as in claim 5 having,~~

~~—a grasping handle attached to the oval shaped body for holding with a surgical instrument during implantation.~~

Please delete claim 7.

~~7. An electrode array body as in claim 5 wherein,~~

~~—the oval shaped body is made of silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.~~

Please delete claim 8.

~~8. An electrode array body as in claim 5 wherein,~~

~~—a grasping handle attached to the oval shaped body for holding with a surgical instrument during implantation.~~

Please delete claim 9.

~~9. An electrode array body as in claim 5 wherein,~~

~~—the oval shaped body has a radius of spherical curvature, which approximates the curvature of the eye, that is decreasing near its edges thus causing the edge of the array to lift off of the retina, eliminating stress concentrations in the retina from contact with the electrode array body.~~

Please delete claim 10.

~~10. A method of reducing stress in the retina caused by the electrode array body as in claim 5 wherein,
— thinning the strain relief internal tab to minimize stress transfer from the mounting tack to the retina.~~

Please amend claim 11 to read as follows:

11. (Amended) ~~An~~ The electrode array body as in according to claim 2 having further comprising,

a strain relief slot in the said oval shaped flexible body curved part of the way forming a semicircular opening around the said mounting aperture which defines a strain relief internal tab in said flexible body for relief of stresses formed when the electrode array body is attached to the retina of the recipient.

Please amend claim 12 to read as follows:

12. (Amended) ~~An~~ The electrode array body as in according to claim 11 wherein,

the said oval shaped flexible body has at least one a radius of spherical curvature, which approximates the curvature of the eye, said radius that is decreasing near its edges of said flexible body thus causing the edge said edges of the array said flexible body to lift off of the retina, eliminating stress concentrations in the retina from contact with the electrode array said flexible body.

Please amend claim 13 to read as follows:

13. (Amended) ~~An~~ The electrode array body as in according to claim 11 wherein,

the said strain relief internal tab is thinner than the rest of the electrode array said flexible body thereby reducing stress in the retina from attachment of the electrode array body.

Please amend claim 14 to read as follows:

14. (Amended) ~~An~~ The electrode array body as in according to claim 11 wherein,
the said flexible body comprises silicone and said strain relief internal tab is made of
comprises a softer silicone than the rest of the electrode array said flexible body.

Please amend claim 15 to read as follows:

15. (Amended) ~~An~~ The electrode array body as in according to claim 11 wherein,
the said oval shaped flexible body is made of comprises silicone having a hardness of about
50 or less on the Shore A scale as measured with a durometer.

Please amend claim 16 to read as follows:

16. (Amended) ~~An~~ The electrode array body as in according to claim 11 wherein further
comprising,
a grasping handle attached to the said oval shaped flexible body for holding with a surgical
instrument during implantation.

Please delete claim 17.

~~17. An electrode array body as in claim 11 having,~~
~~— a grasping handle attached to the oval shaped body for holding with a surgical instrument~~
~~during implantation.~~

Please amend claim 18 to read as follows:

18. (Amended) ~~An~~ The electrode array body as in according to claim 2 further comprising:
a reinforcing ring surrounds the surrounding said mounting aperture in the said oval shaped
flexible body for structural support of a surgical tack.

Please amend claim 19 to read as follows:

19. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 18 wherein,
the said reinforcing ring is colored to make visually locating the said mounting aperture by
the surgeon during surgery easier.

Please amend claim 20 to read as follows:

20. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 1 further comprising:
at least one ferromagnetic keeper in ~~the~~ said flexible body for attaching ~~the electrode array~~
said flexible body to the retina.

Please amend claim 21 to read as follows:

21. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 20 further comprising:
a strain relief slot in the said oval shaped flexible body forming a semicircular opening
~~curved part of the way around the~~ said ferromagnetic keeper which defines a strain relief internal
tab in said flexible body for relief of stresses ~~formed when the electrode array body is attached to~~
~~the retina of the recipient.~~

Please amend claim 22 to read as follows:

22. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 20 wherein,
the said oval shaped flexible body ~~is made of~~ comprises silicone having a hardness of about
50 or less on the Shore A scale as measured with a durometer.

Please amend claim 23 to read as follows:

23. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 20 having further
comprising,
a rounded edge on the said oval shaped flexible body to eliminate stress ~~concentrations in~~

~~the retina from contact with the electrode array body.~~

Please amend claim 24 to read as follows:

24. (Amended) ~~An~~ The electrode array body as in according to claim 23 wherein,
~~the said oval shaped flexible body is made of~~ comprises silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.

Please amend claim 25 to read as follows:

25. (Amended) ~~An~~ The electrode array body as in according to claim 20 having wherein,
~~the said oval shaped flexible body has at least one a~~ radius of spherical curvature, which approximates the curvature of the eye, said radius that is decreasing near its edges of said flexible body thus causing the edge said edges of the array said flexible body to lift off of the retina, eliminating stress concentrations in the retina from contact with the electrode array body flexible body.

Please amend claim 26 to read as follows:

26. (Amended) ~~An~~ The electrode array body as in according to claim 20 having further comprising,
a grasping handle attached to ~~the said oval shaped flexible body~~ for holding with a surgical instrument during implantation.

Please amend claim 27 to read as follows:

27. (Amended) ~~An~~ The electrode array body as in according to claim 1 wherein,
~~the said oval shaped flexible body has a rounded edge to eliminate stress concentrations in the retina caused by contact with the electrode array body.~~

Please amend claim 28 to read as follows:

28. (Amended) ~~An~~ The electrode array body as in according to claim 1 wherein,
the said oval shaped flexible body has at least one radius of spherical curvature, which approximates the curvature of the eye, said radius ~~that is decreasing near its edges of said~~
flexible body thus causing the ~~edge~~ said edges of the ~~array~~ said flexible body to lift off of the retina, eliminating stress concentrations in the retina from contact with the ~~electrode array~~
flexible body.

Please amend claim 29 to read as follows:

29. (Amended) ~~An~~ The electrode array body as in according to claim 1 wherein,
the said oval shaped flexible body ~~is made of~~ comprises silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.

Please amend claim 30 to read as follows:

30. (Amended) ~~An~~ The electrode array body as in according to claim 1 wherein,
the said oval shaped flexible body ~~is made of~~ comprises silicone having a hardness of about 25 or less on the Shore A scale as measured with a durometer.

Please delete claim 31.

~~31. A method of reducing stress in the retina caused by the electrode array body as in claim 1 wherein,
— fabricating the array from silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.~~

Please delete claim 32.

~~32. A method of reducing stress in the retina caused by the electrode array body as in claim 1 wherein,~~

~~—coiling a conductor in a feeder cable to eliminate pulling the electrode array body by the cable due to mechanical or thermal stresses,~~
~~—conforming to the curvature to the retina thereby eliminating stress concentrations.~~

Please delete claim 33.

~~33. An electrode array body as in claim 1 wherein,~~
~~—the oval shaped body has a radius of spherical curvature, which approximates the curvature of the eye, that is decreasing near its edges thus causing the edge of the array to lift off of the retina, eliminating stress concentrations in the retina from contact with the electrode array body.~~

Please amend claim 34 to read as follows:

34. (Amended) ~~An~~ The electrode array body as in according to claim 1 further comprising:
a plurality of electrodes ~~to transmit~~ mounted on said flexible body and suitable for
transmitting an electrical signal to the retina of the recipient of ~~the electrode array~~ said flexible
body.

Please amend claim 35 to read as follows:

35. (Amended) ~~An~~ The electrode array body as in according to claim 1 further comprising:
at least one electrode mounted on said flexible body which provides an electrical reference
or ground potential.

Please amend claim 36 to read as follows:

36. (Amended) ~~An~~ The electrode array body as in according to claim 1 having further
comprising,
a grasping handle attached to ~~the~~ said oval shaped flexible body for holding with a surgical
instrument during implantation.

Please delete claim 37.

~~37. A method of reducing stress in the retina caused by the electrode array body as in claim 36 wherein,~~

~~— attaching the electrode array body by grasping the handle.~~

Please amend claim 38 to read as follows:

38. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 36 wherein,
the said oval shaped flexible body ~~is made of~~ comprises silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.

Please amend claim 39 to read as follows:

39. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 36 wherein,
the said grasping handle is a hemi-tube to allow the insertion of a surgical tool during implantation surgery.

Please amend claim 40 to read as follows:

40. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 36 wherein,
the said grasping handle is a hemi-tube with an internal hole diameter approximately equal to the tube wall thickness.

Please delete claim 41.

~~41. A feeder cable attached to the electrode array body of claim 1 for transmitting electrical signals to the electrode array body wherein,~~

~~— the cable contains a plurality of conductors that transmit electrical signals to the array.~~

Please delete claim 42.

~~42. The feeder cable of claim 41 wherein,~~

~~— the conductors are coiled inside the cable and the cable is filled with silicone having a hardness of about 50 or less on the Shore A scale as measured with a durometer.~~

Please delete claim 43.

~~43. The feeder cable of claim 41 wherein,~~

~~— the feeder cable has a plurality of silicone fixation tabs along its length for attachment of the array to the recipient.~~

Please delete claim 44.

~~44. The feeder cable of claim 41 having,~~

~~— a grasping handle attached to said feeder cable for holding with a surgical instrument during implantation.~~

Please delete claim 5.

~~45. The feeder cable of claim 41 having,~~

~~— a section of straight insulated conductors inside the eye to maximize flexibility of that portion of the cable.~~

Please delete claim 46.

~~46. An electronics package, which processes electrical signals, attached to the feeder cable of claim 41 wherein,~~

~~— the electronics package is encased in an electrically insulating biocompatible material to protect the package from the corrosive environment in the body,~~

~~— the electronics package has at least one fixation tab for attachment to the recipient of the array.~~

Please delete claim 47.

~~47. An electronics package, which processes electrical signals, as in claim 46 wherein,
— the electrically insulating biocompatible material is silicone.~~

Please amend claim 48 to read as follows:

48. (Amended) A retinal electrode array comprising:

a ~~silicone electrode array~~ flexible body having a hardness of about 50 or less on the Shore A scale as measured with a durometer,

~~the electrode array~~ said flexible body having an oval shape,

~~the electrode array~~ said flexible body having a curved shape ~~such that it substantially conforms~~ suitable for conforming to the spherical curvature of the retina of the recipient's eye minimizing stress concentration in the retina,

~~the electrode array~~ said flexible body having at least one mounting aperture suitable for attaching ~~the electrode array~~ said flexible body to the retina,

~~the electrode array~~ said flexible body having a reinforcing ring surrounding ~~the said~~ mounting aperture in ~~the array~~ said flexible body for locating ~~the said~~ mounting aperture during surgery and for structural support of a surgical tack,

~~the electrode array~~ said flexible body having a strain relief slot ~~curved part of the way forming a semicircular opening around the said~~ reinforcing ring for relief of stresses ~~formed when the electrode array body is attached to the retina of the recipient,~~

~~the electrode array~~ said flexible body having ~~a~~ at least one rounded edge to eliminate stress concentrations in the retina from the electrode array body,

~~the electrode array~~ said flexible body having a decreasing radius near ~~its edges~~ of said flexible body causing ~~the edge~~ said edges of ~~the array~~ said flexible body to lift off of the retina and thus eliminating stress concentrations in the retina from the electrode array body,

~~the electrode array~~ said flexible body having a grasping handle attached to ~~the array~~ said flexible body for holding during implantation,

~~the electrode array~~ said flexible body having an array of conductive electrodes ~~to transmit~~

suitable for transmitting electrical signals to the retina,

~~the electrode array~~ said flexible body having at least one conductive reference electrode serving as a reference or ground potential source,

an electronics package to transmit said electrical signals to ~~the~~ said conductive electrodes,
a feeder cable electrically coupled to said electronics package and said conductive electrodes -to carry said electrical signals between said conductive ~~the~~ electrodes and ~~the~~ said electronics package.

Please delete claim 49.

49. A method of reducing stress in the retina caused by the electrode array body comprising:
— ~~rounding the edges of the electrode array body to avoid contact stresses with the retina or tearing of the retina,~~
— ~~reducing the radius of spherical curvature, which approximates the curvature of the eye, near the edge of the electrode array body,~~
— ~~shaping the electrode array body into an oval shape avoiding stress concentrations in the retina from corners of the array.~~

Please amend claim 50 to read as follows:

50. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 1 wherein,
~~the said oval shaped flexible body has a tapered edge to eliminate stress concentrations in the retina caused by contact with the electrode array body.~~

Please amend claim 51 to read as follows:

51. (Amended) ~~An~~ The electrode array body as ~~in~~ according to claim 20 having,
a tapered edge on ~~the~~ said oval shaped flexible body to eliminate stress concentrations ~~in the retina from contact with the electrode array body.~~